

Original research article

An evaluation of information contained in promotional drug literature

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Abstract

The study was aimed to evaluate collected drug promotional brochures for accuracy, consistency, and validity of the information presented in it, using World Health Organization (WHO) criteria for ethical medicinal drug promotion. Drug promotional brochures were evaluated for the type of claims and pictorial content presented in it and for references cited in support of these claims.

This observational, study was conducted by collecting approximately thousands leave behind brochures. From outpatient departments of A.N Magadh Medical College and Hospital Gaya, Bihar. In addition to the fulfillment of "WHO Criteria, 1988", we examined 646 promotional brochures for the type of claims and pictorial content presented in it and references quoted in support of claims to check their irretrievability, type and authenticity.

None of the promotional literature fulfilled all WHO criteria. Majority (91.9%) brochures claimed about the efficacy of product, and a few about safety (37.9%). Out of 996 references given in support of various claims, 84.4% were from journals and only 28.5% were validly presented researches. Brochures presenting irrelevant pictures were 41.3% where brief prescription information (BPI) of the promoted drug was given only by 8.8% brochures.

Pharmaceutical industries did not follow the WHO guidelines while promoting their products, thus aiming to satisfying their commercial motive rather than fulfill the educational aspect of promotion.

Keywords: drug marketing, medicine promotion, promotional literature.

Introduction

The drug manufacturing companies are in the business of developing and selling drugs. Pharmaceutical promotion is a persuasive communication and the major marketing technique of pharmaceutical companies is "direct to physician marketing". Physicians are contracted by medical representatives, presented with sample drugs, token gifts, remainder articles and also targeted through sponsored continued medical education, advertisements in the medical journals. etc. One of the well known promotional activities of pharmaceutical industries is to produce advertising brochures which at times are inaccurate and of poor educational value. These promotional activities create the potential for inappropriate prescribing practices by influencing physicians prescribing behaviour without necessarily benefiting the patients but contributes to increased health care cost.

Material and Methods:

This study was conducted to find out the accuracy and ethical status of promotional drug literature presented to prescribers by using "WHO" criteria for ethical medicinal drug promotion 1988". We also evaluated the drug promotional brochures for the type of claims

and pictorial content presented in it and the references quoted in support of claims to check their retrievability, type and authenticity of presentations.

This observational was cross-sectional study conducted by collecting approximately thousand leave brochures randomly from various OPDs. at A.N Magadh Medical College, Gaya, Bihar namely medicine, surgery, psychiatry, obstetrics and gynecology, ophthalmology skin, pediatrics, and orthopedics over the period from 1st January, 2020 to 31st May, 2020. Some brochures were presented along with the reprint of journal article quoted in it as a reference to the information. Collected brochures were then explored to exclude the following materials: Literature promoting medicinal devices and equipments (insulin pump, blood glucometer etc) orthopedic prosthesis and ayurvedic medicines, drug monographs, reminder advertisements drugs name list, and literature promoting more than four brands.

WHO criteria for ethical medicinal drug promotion dictate that promotional literature should contain following information:

1. The name(s) of the active ingredient(s) using either international non proprietary names (INN) or the approved generic name of the drug.
2. The brand name
3. Amount of active ingredient(s) per dose
4. Other ingredients known to cause problems i.e. adjuvant
5. Approved therapeutic uses
6. Dosage form or dosage schedule
7. Safety information including side effects and major adverse drug reactions, precautions, contraindication and warnings, and major drug interactions
8. Name and address of manufacturer or distributor
9. Reference to scientific literature as appropriate

We evaluated criteria six separately as dosage form and details about "regimen" to look for the completeness of therapeutic information given in the promotional brochures. In addition to this information, promotional materials made various claims about the medicinal products presented in it. Claims made in the promotional brochures were classified into following seven categories.

1. **Efficacy:** Statements about improved effectiveness of promoted drug as a disease outcome or a patient outcome solely or in comparison with other group of drug for similar outcome (e.g. antihypertensive action of calcium channel blocker and β blocker) or another brand of the same drug (e.g. Zintac or rantac for ranitidine).
2. **Safety:** Use of the word "Safe" in the promotional text or the mention or reduction in adverse drug reaction and / or drug interaction and / or contraindication.
3. **Cost:** Pointing out low price of promoted drug in absolute or relative terms or any description related to its better cost effectiveness.
4. **Convenience:** Statements stating the comfort of patient e.g. improved dose, low frequency of dosage ease of administration etc with or without reasons to support the same.
5. **Pharmacokinetic property:** Properties of the drug related to its absorption, metabolism, half life etc.
6. **Pharmaceutical property:** New dosage formulations, different manufacturing procedures, excipients (e.g. cyclodextrin, sodium bicarbonate, etc) storage facilities etc.
7. **Extravagant emotional claims:** Any claims or statements not related to patient outcome, disease outcome, or drug e.g. 1st of its kind in the world or India, flavored oral preparations, authentic certification of manufacturing plant (GMP certification, USFDA approval, etc) various drug formulations, packaging characteristics or technologies of the drug production.

Promotional literature quoting references in support of the claims made in it was further evaluated for its authenticity. References sustaining the claims were categorized as per the

source of material i.e. journals, web sites, books, data on file and other including guidelines, seminar, departmental studies, and prescription information.

The available references were checked with the claims made in the promotional brochures. Depending upon their presentation, We classified them as either validly, invalidly or partially validly presented. Validity assessment of the references and type of reference were independent, i.e., if referenced articles was quoting a RCT but if its outcome manipulated while supporting the claim, it was considered invalid reference and vice versa.

Promotional materials are usually made attractive using various pictures or various methods of data presentation to persuade doctors for prescribing the drug promoted in it. Pictorial content of the promotional brochures was evaluated for :

1. The type of pictures (healthy babies, women, patients, doctors, medicinal products, or other treatment unrelated pictures)
2. Number of scientific tables.
3. Scientific graphs and Pseudographs

Pseudograph is a graphical presentation without proper axes labeling legend, or just arrows with numbering showing reduction or increase. (cooper etal. 2003)

Results:

1. **Type of drug:** A total of 608 drugs were presented in 646 drug promotional brochures. Out of 608 promoted drugs. 39.8% were fixed dose combinations (FDCs) whereas 60.2% were single drug preparations. Out of 242 promoted (FDCs) only 33 (13.6%) were recommended by WHO.

Chemotherapeutic agents were the most promoted group 27.1% and they can contribute to development of drug resistance, due to overuse. Cardiovascular drugs (13.12%) and hormones (10.3%) come close second and third among promoted drugs. These are the medicines once started, are taken for lifelong, providing long term financial benefit to the pharmaceutical companies.

2. **Fulfillment of WHO criteria:** Our findings showed that pharmaceutical industries were most reluctant to provide information regarding treatment regimen, information regarding safety and adjuvant, rather promotion was only focused on latest drug formulation and these were supporting the findings of previous studies. It was found that none of the brochures fulfilled all the 10 WHO Criteria. After excluding lowest presented criteria i.e. adjuvant rest nine criteria were fulfilled by only 7.1% literature. Approximately half (46.7%) of the evaluated brochures were satisfying only six criteria, namely brand name, INN, dosage form, approved use content of the active ingredients and address of the manufacturer.

Table 1: Evaluation of promotional literature as per WHO Criteria (n=646)

Criteria	Mentioned number (%)
INN	607 (93.9%)
Brand Name	646 (100%)
Content	503 (77.8%)
Adjuvant	12 (1.8%)
Approved therapeutic uses	562 (86.9%)
Dosage form	568 (87.9%)
Regimen	206 (31.9%)
Safety Information	58 (8.9%)
Manufacturer Address	458 (70.8%)
References to Scientific information	400 (61.9%)

3. **Claims:** Apart from giving therapeutic information, pharmaceutical companies also made multiple claims, as much as six per literature. Brochures making to claims each where the maximum in number (32.56). A total of 1205 claims were made in promotional brochures. Claims about efficacy were made in 91.9% brochures, followed by that of safety in 33.6% and of pharmaceutical properties in 28.5%.

Number of promotional brochures making extravagant emotional claims, claims regarding cost effectiveness, pharmacokinetic properties and convenience were almost equal in number i.e. 16.1%, 15.4%, 15.7% and 15.7% respectively. Our findings were similar to the observations made in other studies where author found broad unscientific, dubious claims in promotional literature. (mindell et al. 1997).

4. **References:** Pharmaceutical industries gave references to support information presented or claims made in the drug promotional brochures. One third of promotional brochures (34.4%) cited one or two references. References in the range of three to seven per brochures were given by 25.5%. Pharmaceutical industries behavior was very surprising that on one hand eight to nineteen references per brochure were given in 3.94% brochures and on other side 36.2% of it did not bother to give any to support the claims made in it. Classification of references distinctly demonstrates that citations from journal articles were the 85.8% maximum.

5. **Retrievability and validity of references :** The maximum retrieved references were journal articles abstracts, from which the related details were identified and then classified. Major share of journal articles was contributed by research articles and review articles. Half of the given (49.6%) were presented validly and review articles (29.4%) has a major quarter. Rest half of the references were either invalidly presented 23.7% irretrievable 22.8% or partially valid in presentation 5.8%. References giving the results of clinical trials of ambiguous methodology or nonrandomized clinical trials were 8.4%. These findings were similar to those of Villanueva et al. 2006 van Winkelen et at. 2003 and cooper and schriger 2005. All the animals study references (1.6%) except for one were invalid. Claims outnumbered the relevances provided in the promotional literature, and 468 claims from 204 promotional brochures were without any references. In the absence of one of one correspondence in the claims and references, we specifically checked all safety claims, as per WHO criteria for their substantiation. Although WHO criteria strictly states that the word 'safe' should be used if properly qualified, findings of our study were presenting leave behinds claiming for safety of drug presented in it, only 25.5% gave supporting reference while 74.5% boosted the same without any references. Current finding underlines the profit driven promotional attitude of the pharmaceutical industries which is depriving the physicians a authentic drug information.

6. **Pictures:** As a part of persuasive communication, these promotional brochures were made striking using various types of pictures and devoting major of the literature area to nonspecific content depriving it of useful therapeutic information. It was type of picture and not the number of pictures per brochure, which we counted such irrelevant pictures supported the studies done by Stimson 1975 and cooper et al. 2003 Study by Curry and O'Brien has shown that "male heart patients" and "depressed female patients" were stereotyped through the images used in the advertisements, which could strengthen gender association. We were unable to find such an association though pictures of women was forming third large category in varied types of pictures presented in the evaluated brochures.

Brochures presenting pictures unrelated to medicine, disease, or therapy were 42.43% representing the tendency of pharmaceutical industry of wasting money in printing eye catching glossy paper promotional brochures deprived of important therapeutic information. This fact is proved by the information that BPI of the promoted drug was given only by 8.8% brochures.

We found that some of the evaluated drug promotional brochures used graphical presentations to depict the information. A total of 210 graphical presentations were evaluated from 16.5% of drug brochures. Pseudographs (27.2%) were the maximum in number followed by tables (23.5%) and bar diagrams (24.4%), Line diagrams (13.9%) tables giving cost comparisons 7.8% pie diagrams 3.2% and scatter diagram embraced the rest of graphical presentations. The predominance of pseudograph pointed out the commercial and promotional rather than educational attitude of the industries. Our findings were consistent with those of the study by Cooper et. al.

Discussion

It was concluded from this study that pharmaceutical industries did not follow WHO guidelines while promoting their drug products, thus accelerated their commercial motive rather than ethical educational aspect. Little therapeutic information was provided to help physicians reach any rational decision about promoted drug. Promotional activity was concentrated not much on innovative medicines exposure, but on publicizing fixed dose combinations, not recommended by WHO. The promotional brochures were full of unsubstantiated claims regarding safety or efficacy, and those claims were therapeutically irrelevant also. Important information regarding adverse drug reactions, contraindications or drug interactions was usually missing. Reference citations were given to earn credibility, but it was difficult to trust them because of ambiguous presentation, poor quality, and questionable retrievability. Therapeutically unrelated matter was printed compromising the space to be given to important BPI.

Printed promotional material is an important source of information. On the basis of the observations of this study, It is suggested that physicians need to be aware of the flaws in promotional literature before accepting it as valid information. This could help monitor it with great vigilance. The association of pharmaceutical companies in developed countries, e.g. UK, Australia and Canada are required to observe a code of practice in marketing as a Signatory condition for membership of the association. India has set up regional ethics committee to collect complaints against unethical drug promotion advertisements at Mumbai, New Delhi, Chennai and Chandigarh which forward these complaints to drug controlled authority to take necessary legal steps to discipline guilty companies. Forwarding more complaints about irrational promotion to regulatory authority by cautious doctors might lead pharmaceutical industry to incline toward self regulation. Government regulatory bodies must play a proactive role where code of ethics is failing. Wherever the hospitals are attached to the academician, prior scrutiny of the promotional materials for authenticity of the content could be done by respective department of pharmacology.

This study evaluates one types of promotional activity of pharmaceutical company i.e. printed promotional literature, however interventional research to assess the awareness of the physicians about these facts and alerting them about the same will help gain accurate and ethical information from promotional literature.

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